

# Pediatric Initiative Network Meeting

11/11/19

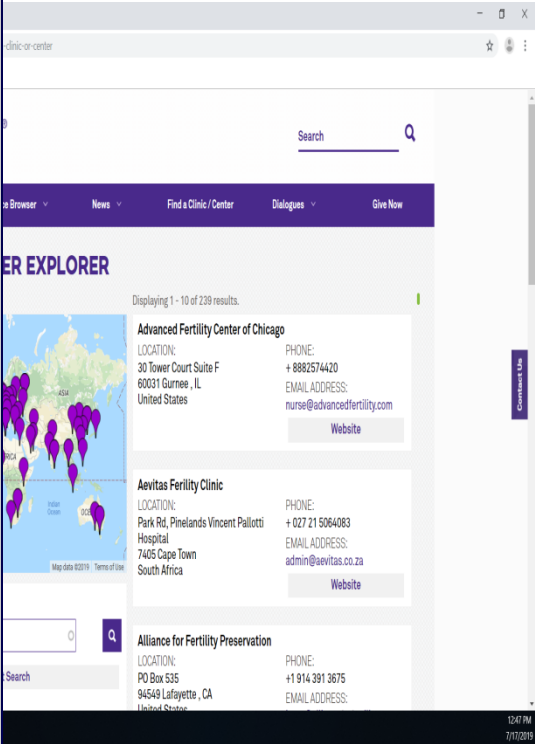
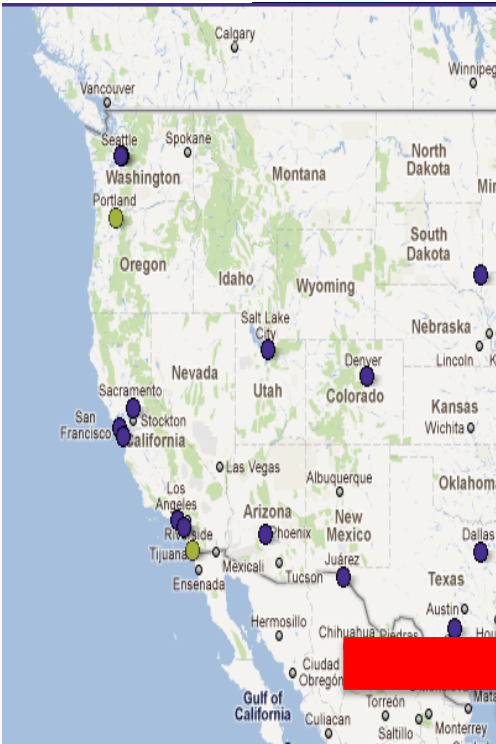
**Leena Nahata, MD**

Associate Professor of Clinical Pediatrics  
The Ohio State University College of Medicine  
Endocrinology and Center for Biobehavioral Health  
Medical Director, Fertility and Reproductive Health Program  
Nationwide Children's Hospital  
**Chair, PIN**

**Molly Moravek, MD, MPH**

Assistant Professor, Obstetrics and Gynecology  
Division of Reproductive Endocrinology and Infertility  
Assistant Professor, Urology  
Director, Fertility Preservation Program  
IVF Medical Director  
University of Michigan  
**Vice Chair, PIN**

# Oncofertility Consortium



- 2-way exchange of information, technologies, and issues
- Multi-disciplinary approach
- Promulgate best practices and strong referrals to local centers

# Mission

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***The Pediatric Initiative Network (PIN) is an international group of providers dedicated to preserving and protecting the fertility of children and adolescents at risk for infertility due to medical conditions or treatments.***

# Structure

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- Chair: Leena Nahata, MD
- Vice-Chair: Molly Moravek, MD, MPH
- Committees:
  - Best Practices - *to develop strategies to optimize fertility related care for at-risk youth*
    - Navigator subcommittee - *dedicated to improving access to fertility related care for at-risk youth*
  - Research - *to design and implement collaborative multi-site research studies to advance fertility related care for at-risk youth*
- Past-chair: Leslie Appiah, MD

# Committees

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- Best practices

- *Chair*: Lillian Meacham, MD
- *Vice-Chair*: Holly Hoefgen, MD
- *Navigators lead*: Stacy Whiteside, CPNP-AC

- Research

- *Chair*: Veronica Gomez-Lobo, MD
- *Vice-Chair*: Krista Childress, MD
- *\*Vice-Chair*: Maggie Dwiggin, MD

# 2018-2019 membership

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- 102 members
- 62 institutions
- Physicians, researchers, advanced practitioners, nurses, psychologists/SW, trainees...
- Quarterly PIN calls
- Ad hoc committee/working group calls
- PIN list-serv

# Morning Agenda

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- 8-8:15 PIN Intro
- 8:15-9:15 Program Development
  - Standard FP practices/barriers – open discussion!
- 9:15-10:15 Best Practices
  - Updates and Ideas for upcoming year
- 10:15-11:15 Research
  - Updates and Ideas for upcoming year
- 11:15-11:30 Wrap up, intro to PM working groups

# Afternoon Agenda

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- 11:30-12:30 BP Working Group
- 12:30-1:30 Working lunch (Navigators)
- 1:30-2:30 Research Working Group
- 2:30-3:30 BP/Research Working Groups

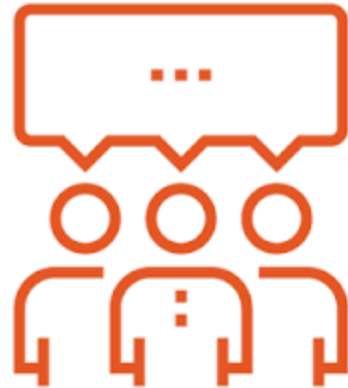


# Reminders

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- Please sign in
- Please consider joining committees/ working groups and actively engaging in projects!

# PROGRAM DEVELOPMENT: EXISTING AND FUTURE



# Formal Fertility Preservation Program?

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- Nationwide
- Michigan
- Pittsburgh
- Lurie
- Cook Childrens Fort Worth
- Children's National DC
- NIH
- Childrens MN
- Duke
- Ohio State
- Iowa
- Hopkins
- Utah
- Cornell
- USC
- Louisville – Norton
- CHOC
- Seattle
- Children's mercy Kansas City
- CT Childrens
- Cinci
- Wash U St Louis
- Oregon
- CHOA
- Saudi Arabia – King Faison

# Dedicated Patient Navigator/Coordinator?

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- 13

# Strategies to Maximize Access

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- Opt-out (instead of opt-in) - 4
- Hard stop in EMR – 2
- Patient lists of upcoming patients – 7
  - Tumor board, State reporting
- Dedicated email address that includes entire team
- Outpatient/Inpatient order sets
- Floor nurse-based ordering for fert pres consult
- Education of providers
  - House officer didactics/orientation
- Nurse practitioner network within institution
- Wish it was better – 30 (everyone but Cinci)

# REI involved (e.g. for egg freezing)?

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- 20

# Reproductive Urology Involved (e.g. aspiration)?

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- 19

# Offering OTC?

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- Lurie
- Pitt
- Nationwide
- Children's National
- Cornell
- Louisville
- CT
- Kansas City
- Oregon (vit)
- Hopkins
- Australia – Melbourne
- UCSF
- Stanford
- Cinci
- Japan 42 (covered in 10-15)
- Wash U
- Tunisia
- Billing insurance (oophorectomy/testicular bx)- 6. People have had luck with medicaid
- Reimbursed – 6
- Pitt – uses philanthropy, charging for freezing process
- Kansas City – self-pay \$5700



# Self pay OTC

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- Kansas City – 5700
- \*Cinci – 5500
- Wash U 8000
- Lurie 7500
- Nationwide 5000
- \*includes processing
- Several institutions process tissue at no charge
- Tissue processing \$400, 695, 900x2, 1000
- Annual 28 cinci, 19 (55 total) Pitt (adult and kids), Lurie 20 (>100 total), 12 National. Kansas City 8-10

# Which populations?

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- BMT for nononcologic – all
- Turner – Kansas City, Cinci, Wash U,
- DSD, incl Turner - Lurie (only if Y chrom/undergoing gonadectomy), Pitt
- Transgender – Pitt, Stanford, UCSF
- Rheum/Nephro (high dose Cytoxan) – Kansas City, Wash U, Cinci
- Leukemia – before BMT, only IVM
- POI - NIH

# Offering TTC?

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- Pitt
- Children's National
- Nationwide
- UCSF
- Lurie
- Louisville
- CHOC
- Kansas City
- CT
- Cinci
- Wash U
- Melbourne
- TTC processing \$500
  - All reserved for patient use

# Which populations?

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- BMT Nononcologic
- Transgender – Pitt, UCSF, Melbourne
- DSD – Lurie, Pitt
- Nephro/Rheum (high dose Cytoxan) – same as OTC

# Programmatic Barriers?

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- Slow freezer
- Can't use philanthropic funds  
2/2 “enticement”
- Securing philanthropy
- Standardization/QI (no accreditation process)
- Who pays for program?
  - FTEs
  - Decreased/no billing
- Patient navigator
- Billing
  - Cancer code first
  - Combo with line
- IRB
  - TTC too experimental?

# Solutions to Barriers?

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- Support for navigator –
  - Can navigator bill?
  - Nursing research or specialty roles is necessary for magnet status
- Fert Pres a part of USNWR, Center of excellence
- IRB – may not need it for OTC because it's “not research”, can pair with research like database or survey. Articulate benefit. Talk to IRB before submission or go to meeting. Clinical research coordinator to communicate with IRB

Best Practices Subcommittee  
Pediatric Initiative Network  
Oncofertility Consortium

2019

# Best Practice Committee

1. Risk Stratification Working Group - Meacham
2. Nurse Navigation - Whiteside
3. Pediatric Blood and Cancer Special Edition Series – Appiah and Anazodo



# Risk Stratification Working Group

- 27 Oncofertility PIN members
- Everyone submitted risk stratification systems they use
- Literature search
  
- 200 emails
- 3 Conference calls
- 7 versions of the stratification grid

Name	Specialty	Institution	Role in Fertility Preservation
Antoinette Anazodo, MD	Pediatric and Adolescent Oncology	Sydney Children's Hospital, Prince of Wales Hospital School of Women's and Children, Univ. of New South Wales	Service development, educator, champion and expert
Leslie Appiah, MD	Pediatric and Adolescent Gynecology	The Ohio State University College of Medicine Nationwide Children's Hospital	Co-Director, Fertility Preservation and Reproductive Health program
Kari Bjornard, MD, MPH	Pediatric Hematology/Oncology	St Jude Children's Research Hospital	Oncology liaison to fertility clinic
Karen Burns, MD	Pediatric Oncology	Cincinnati Children's Hospital Medical Center University of Cincinnati College of Medicine	Co-Director, Comprehensive Fertility Care and Preservation Program
Brooke Cherven, PhD, MPH, RN	Pediatric and Adolescent Oncology	Children's Healthcare of Atlanta, Emory University	Nurse researcher in reproductive outcomes
Krista Childress, MD	Pediatric and Adolescent Gynecology	Children's Healthcare of Atlanta, Emory University	Member- Fertility Preservation Team
Allison Close, MD	Pediatric Hematology Oncology	Helen DeVos Children's Hospital, Michigan State University	Leader of pediatric fertility preservation services
Daniel Green, MD	Pediatric Hematology Oncology	St Jude Children's Research Hospital	Clinical researcher in gonadal outcomes
Holly Hoefgen, MD	Pediatric and Adolescent Gynecology	Washington University School of Medicine	Co-Director, Integrated Care & Fertility Preservation Program
Yasmin Jayasinghe, MD			
Lisa Klimpel, NP	Ped, Adol and Young Adult Oncology	Children's Hospital of Orange County	Fertility Program Nurse Practitioner Leader
James Klosky, PhD	Pediatric Psychology	Children's Healthcare of Atlanta, Emory University	
Mary Langevin, NP	Pediatric Oncology	Children's Minnesota	Co-Director AYA Oncofertility / Preservation Program
Jennifer Levine, MD			
Veronica Lopez-Gobo, MD	Pediatric and Adolescent Gynecology	<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development	Director Of Pediatric and Adolescent Ob/Gyn
Lillian Meacham, MD	Pediatric Endocrinologist	Children's Healthcare of Atlanta, Emory University	Director of the Fertility Preservation Program
Molly Moravek, MD		University of Michigan	Director, Fertility Preservation Program
Leena Nahata, MD	Pediatric Endocrinologist	Nationwide Children's Hospital	Director of Fertility and Reproductive Health Program
Kyle Orwig, PhD	Reproductive Medicine	University of Pittsburgh	Director, Fertility Preservation Program of UPMC
Olivia Prebus, RN	AYA Oncology	Cook Children's Medical Center	Oncofertility Nurse Navigator
Megan Pruett, NP	Pediatric Endocrine Nurse Practitioner	Children's Healthcare of Atlanta	Member- Fertility Preservation Team
Erin Rowell, MD	Pediatric Surgery	Ann & Robert Lurie Children's Hospital	Director, Fertility and Hormone Preservation and Restoration Program
Jill Samis, MD	Pediatric Endocrinology	Ann & Robert H. Lurie Children's Hospital of Chicago	Member - Fertility and Hormone Preservation and Restoration Program
Amanda Saraf, DO	Pediatric Oncology	Riley Hospital for Children	Associate Director of Oncofertility
Hanna Valli-Pulaski, PhD	Researcher	University of Pittsburgh	Fertility Preservation Program Coordinator
Stacy Whiteside, NP			
Mary Zelinski, PhD	Researcher	Oregon National Primate Research Center Oregon Health & Science University	Ovarian Tissue Cryopreservation research Consultant to Fertility Preservation Team

## Purpose

Create for PIN a **stratification system for risk of future infertility** that is based on available literature and expert consensus that can be used to:

- **guide clinical consultations** – so that providers (from different sites) performing fertility consults are able to give similar messages about the level of risk for future ovarian failure/ infertility in females and future infertility in males.
- **categorize patients for research studies**

This classification system will allow comparisons across various clinical practices and research studies.

**Key considerations:** In studies of childhood cancer survivors 46-60% males had self reported infertility<sup>1</sup> and 15.9% in females had AOF/POI or self reported infertility<sup>2</sup>

This risk stratification is intended to be **published as a Perspective in JAYAO or in Dialogues in Oncofertility** (the new TKW initiative). The grids will be published with a commentary and a perspective from a clinician on how this could be used in clinical practice and a commentary from a researcher on how this could aid research initiatives.

• <sup>1</sup> Wasilewski-Masker J Can Surv 2014 <sup>2</sup> Barton Lancet Oncol 2013

# Caveats

- There is no evidence in the literature for survivors of pediatric, adolescent and young adult cancer that non-alkylator/non-heavy metal chemotherapy is associated with future risk for infertility
- Alkylators have been converted to Cyclophosphamide Equivalent Doses (CED) based on: Green DM, et al. (2014) The cyclophosphamide equivalent dose as an approach for quantifying alkylating agent exposure: a report from the Childhood Cancer Survivor Study.
- The risk for future infertility associated after the use of newer agents and immunotherapy during childhood cancer treatment is still to be determined
- With risk adapted therapy the level of risk has to be adjusted with changes to therapy.
  - It is important to be re-consulted if therapy changes
  - It is important to date any fertility risk assessment

**Female Level of Risk for Gonadal Failure / Infertility  
above that for the general population**

			Minimally Increased Risk	Significantly Increased Risk	High level of Significantly Increased Risk
Alkylators* CED gm/m2	Prepubertal	CED < 8 <sup>3</sup>		8-12	> 12 <sup>3</sup>
	Pubertal	CED < 4 <sup>4,5</sup>		4-8	> 8 <sup>4,5</sup>
Heavy Metal			Cisplatin Carboplatin		
HSCT					Alkylator +/-TBI Myeloablative and Reduced intensity
Radiation exposure	Ovary	Prepubertal		<15 Gy <sup>5,6</sup>	≥ 15 Gy
		Pubertal		<10 Gy <sup>5,6</sup>	≥ 10 Gy
	Hypothalamus		22-29.9 <sup>7</sup>	> 30-39.9 Gy	> 40 Gy

\*Procarbazine is particularly gonadotoxic <sup>4</sup>

# In central deficiency, the ovaries are not harmed. Treatment with gonadotropin can overcome this late effect

**Male Level of Risk for Infertility  
above that for the general population**

		Minimally Increased Risk	High level of significantly increased risk	
Alkylators gm/m2		CED <4 * <sup>9</sup>	CED ≥ 4*	
HSCT			Alkylator based and /or TBI Myeloablative and Reduced intensity	
		Minimally Increased Risk	Significantly Increased Risk	High level of Significantly Increased Risk
Heavy Metal mg/m2		Cisplatin Carboplatin	Cisplatin >500	
Radiation Exposure	Testicular	0.2-0.6Gy	0.7-3.9 Gy	≥4.0 Gy <sup>1</sup>
	Hypothalamus#	26-29.99 <sup>8</sup>	> 30-39.9 Gy	> 40 Gy
Surgery			RPLND	

\*CED < 4 gm/m2 89% were normospermic (Green Lancet Oncol 2014). Risk increase with cumulative alkylator dose

# In central deficiency, the testes are not harmed. Treatment with gonadotropin can overcome this late effect

RPLND- retroperitoneal lymph node dissection

## References

1. Wasilewski-Masker J Can Surv 2014
2. Barton Lancet Oncol 2013
3. Chemaitilly W, JCEM 2017 POI St Jude Life.
4. Levine J, Cancer 2018 – Nonsurgical premature menopause
5. Chemaitilly W, JCEM 2006. AOF CCSS.
6. Chemaitilly W,AOF in St Jude Life in prep
7. Green DM, Fertility and Sterility 2011 CRT 22 Gy
8. Green DM, Hum Reprod 2017 cranial RT and sperm production
9. Green DM, Lancet Oncology 2014 CED and sperm production

# Oncofertility Navigation Sub-Committee

- Established after Oncofertility Consortium meeting in November 2018
- First conference call December 14<sup>th</sup> 2018 with 7 participants
- Current membership up to 25 participants from 23 institutions across U.S. & Australia, both pediatric & adult representation
- Conference calls every other month
- Goals:
  - Provide forum to address unique needs of fertility navigators
  - Network of cooperative programs in all stages of development
  - Develop navigator specific projects & contributions to the Oncofertility Consortium



# Oncofertility Navigation Sub-committee

- 2019 Accomplishments

- Tripled membership in 9 months
- Active member participation in bimonthly conference calls
- Pilot program survey completed with 19 respondents
- Working navigator committee lunch 11/11/19 12:30pm to 1:30pm
- Legislative Working Lunch 11/13/19 12pm to 1pm
  - Immediately follows talk on Advocacy & Legislation by Joyce Reinecke JD
  - Address real time insurance issues faced by providers on the front lines featuring actual cases provided by committee members
  - Discuss practical approaches for advocacy
- Oncofertility Navigation publication in progress with PBC special edition

# Pediatric Blood and Cancer Special Edition

- Special guest editors Antoinette Anazodo and Leslie Appiah
- 8 manuscripts in progress for Pediatric Blood and Cancer
- All first drafts have been submitted to first/senior authors
- November 1<sup>st</sup> - Revisions submitted to authors
- November 29<sup>th</sup> - Second round of revisions due to first/senior authors
- February 10<sup>th</sup> – final manuscripts due to PBC Editors
- Cost for Open Access \$15,000 – covered by Anazodo, Appiah, Woodruff

# Pediatric Blood and Cancer Special Edition

- Pediatric Reproductive Tumors
- Male Pediatric and AYA Reproductive Survivorship
- Female Pediatric and AYA Reproductive Survivorship
- Reproductive Late Effects after BMT
- Fertility Considerations in AYA Survivorship
- Psychosexual Function in Survivorship
- Reproductive Health Literacy
- Reproductive Care Navigation in Survivorship

# Best Practice Projects– 2020

- Ideas for 2020 Projects (need a leader and a working group)
  - AMH after Completion of Treatment – Survey (18)
    - Who? When? Where? How using?
  - Best practice for inducing puberty in males, with pre-pubertal radiation damage (central hypogonadism) (1-2)
    - Concerns with long-term fertility effects of T
  - Best practice for FP after Car-T cells/gene engineering products
    - Lack of outcomes on novel therapies (may be outside this group)
  - Safety of FP after some chemotherapy, other treatment (all methods) (5)
  - Standard key performance indicators (KPI) of care (17)
    - What should the KPIs be, each site monitor themselves and provide to central
    - Review recommendations that exist, create the recommendations moving forward
    - USNWR metrics, COG, Cancer care delivery study
  - Time from procedure to start of therapy
  - Show benefits of FN (in current paper, possible in KPI as well)
  - Health literacy, patient education (written, video, SDM tools) (4)

# AMH – Interested parties

- Interested parties
  - Julie Rios – CCHMC (possible leader)
  - Kari Bjornard – St. Jude (possible leader)
  - Kristin Yu (possible co-leader)
  - Kelly Acharya – Duke
  - Jackie Maher – NIH
  - Serena Chan – Pitt
  - .... Sign up sheet sent around
- Potential barriers
  - Survey
    - who to send to (PIN listserve)
      - Consideration – ASRM, NASPAG, ?oncology/endocrinology groups
    - Capture what we are doing, what we should be doing

# AMH (in following gonadotoxic tx)

## Survey of clinical practice

- Potential Questions
  - Provider demographics
  - When do you start checking
    - Is it same for all risk, before tx, all ages, pubertal stages
  - Do you do baseline
  - Correlation b/t AMH and follicle density
    - Do you correlate with US, other labs
    - How to weigh the AMH vs other information (FSH, E2, AFC, clinic information, etc...)
  - Do you surveillance, how often (what age, what time)
    - Are their caveats based on results
  - What do you use the AMH result to decide
  - How do you decide normal vs not
    - Age based norms, pubertal norms, lab norms, trending values, quartiles
  - Correlation with spontaneous pregnancy and response to ART
    - Relationship to menses
  - Do you change checking or evaluation based on hormones taken (BCM, HRT, etc...)
  - If you don't get AMH – why (cost, coverage, pt preference, don't see value, etc...)
    - If cost were not a barrier would you practice differently

# KPI (key Performance Indicators)

- Quality assurance indicators for practice (Australia)
  - Receiving and documenting FP consult
  - Providing written resources for families on FP
  - Clinical ethics checklist
  - Reporting on safety data (minor / major)
  - Documented f/u with patients on tissue 'success/quality'
- Working group partners
  - Antoinette, Yasmin Jayasinghe, Holly Hoefgen
- Monitoring quality of consultation – decisional regret scales, knowledge scores



## Oncofertility 2019

### Pediatric Initiative Network Research Committee Updates

Krista Childress, MD

Veronica Gomez-Lobo, MD

Maggie Dwiggins, MD



# What has happened 2018-2019

- 11/2018 Krista Childress appointed vice-chair of research committee
- 11/2018 Discussions began with James Klostky regarding research on attitudes towards fertility preservation
- April 2019 - applied for ASRM Grant to help fund a research coordinator for the OTC database
  - 10/2019-Informed that we did not receive the grant
- July 2019- Mary Zelinski creates a list of sites performing ovarian tissue research
- August 2019- Maggie Dwiggin- co-vice-chair of research committee

# PIN Research Committee 2019-2020: Building on Past Endeavors

- Attitudes towards fertility preservation and uptake of experimental methods
- Databases
  - OTC Database
  - TTC Database
  - Future database for all fertility preservation
  - Database to facilitate collaboration between those collecting tissue and those performing tissue research



# Attitudes towards fertility preservation and uptake of experimental methods

James Klosky PhD, ABPP  
james.klosky@emory.edu

Brooke Cherven, PhD, MPH, RN  
brooke.cherven@choa.org



## Fertility Status Assessment After Gonadotoxic Treatment

- **PI:** Brooke Cherven, PhD, MPH, RN; Emory University
- **Population:** Adolescent and young adult (AYA) females *after* gonadotoxic treatment
- **Purpose:**
  - Identify factors related to AYA interest in fertility status assessment after treatment
  - Describe factors related to decision-making for oocyte cryopreservation after gonadotoxic treatment among eligible AYA
  - Pilot an intervention to increase fertility status assessment and fertility preservation among interested AYA
- Recruiting 1-2 collaborating sites; Planned submission in spring 2020 for career development grant
- Contact: [brooke.cherven@choa.org](mailto:brooke.cherven@choa.org)

## Familial Decision-Making Surrounding TTC and OTC

- **PI**: James Klosky, PhD, ABPP; Emory University
- **Population**: Families of (primarily) pre-pubertal patients eligible for TTC or OTC
- **Purpose**:
  - Identify factors which differentiate families who do/do not pursue TTC or OTC post invitation
  - Results will inform interventions designed to promote TTC participation
- **Participation**:
  - Sites with an open TTC or OTC protocol; research objective weaved into existing protocols
  - All parents and older patients ( $\geq 8$  yrs of age) complete a brief questionnaire post FP consult
  - Depending on funding, may expand participation to include newly diagnosed post-pubertal females eligible for oocyte cryopreservation
- Actively recruiting sites to participate
- Two planned NIH grant submissions: TTC in Winter of 2020, OTC in Summer of 2020
- Contact: james.klosky@emory.edu

## Effect of Decision Aid (DA) on Psychological and FP Outcomes

- **PI**: James Klosky, PhD, ABPP; Emory University
- **Population**: Post-pubertal patients who are candidates for fertility preservation
- **Purpose**:
  - Adapt Dr. Yasmin Jayasinghe's DA (originally developed in Australia) for use in the US
  - Test the DA's effect on Decisional Quality, Satisfaction, and Regret along with FP outcomes
- **Participation**:
  - Sites with small to medium FP programs randomly assigned to DA or SOC conditions
  - Parents and adolescents in both conditions complete surveys post FP consult
  - Acute and longitudinal effects of DA exposure will be considered in study outcomes
  - Funding provided pending successful grant application
- **Actively recruiting sites to participate; Planned NIH grant submission in late 2020**
- **Contact: james.klosky@emory.edu**



# Databases

OTC

Database of Sites Collecting and those Performing Ovarian Tissue Research

TTC

Database Network

# OTC Database- History



- Original NPC protocol: tissue was sent de-identified to NPC
  - Minimal data was collected
  - Original protocol included a yearly phone call to participants to collect information
    - Not many sites collected this data
    - NPC did not collect data
- **There is a unique opportunity to answer research questions by collecting prospective and retrospective detailed information on individuals who undergo OTC**
- Initiated at Medstar in 2017 with collaborative input from the PIN
  - Data entered retrospectively by Pittsburgh and Children's National
  - Sites obtained IRB approval for the prospective collection of data within their site-specific OTC IRB
    - Database allows sites to obtain IRB approval for OTC as OTC is not "research"



# OTC Database- 2019-2020



- Veronica Gomez-Lobo, MD relocated to NICHD
- Applied for ASRM grant to fund a research coordinator-did not receive the grant
- MedStar can no longer sponsor the RedCap

## • **2019 Database to relocate to Norton Childrens**

- Maggie Dwiggin, MD- Fellow at MedStar and did data entry for this project there
- Now at Norton Children's has funding and research coordinator

# PIN OTC Collaborative Database Proposal

- Updated database
  - Provide infrastructure to perform high quality multi-institutional studies
- Encourage more robust capturing of patient and disease characteristics for increase in meaningful research
  - Eventually answer questions regarding safety, long term outcomes, and long-term patient perspectives regarding OTC
- Data coordinating center (Norton) agrees to maintain the database
- Manual input- by each site directly or forms sent to data coordinating center
- Every site has equal ownership of information
  - Legal data use agreements
  - Authorship on every publication
  - Agreed upon intervals query research question



# New OTC Database



- **PI-** Maggie Dwiggin- Norton Children's
  - Maggie.Dwiggin@NortonHealthcare.org
- **Population:** all patients who undergo OTC
- **Purpose:** obtain detailed longitudinal data in order to improve care and answer clinical research questions regarding impact of OTC
- **Participation:** all sites with active OTC protocols
  
- **Need to address:**
  - IRB central or peripheral
    - Any grant support=central IRB
  - New data sharing agreements
  
- **Need to brainstorm:**
  - Data collections sheets- need to be updated to maximize useful information

# Database of Sites Collecting and those Performing Ovarian Tissue Research

- Some sites are collecting and storing tissue for research
- Some sites are performing tissue research
- **How can the PIN facilitate collaboration?**
- Database of those collecting tissue and performing research:
  - Mary Zelinski- will maintain the list and those wanting to share/collaborate can contact he through the PIN
- SOC for transport of fresh and frozen tissue has been written
- Plan for investigators to share their information
- Investigators who would like to be listed can reach out at
  - [zelinski@ohsu.edu](mailto:zelinski@ohsu.edu)



# TTC Database

- November 2016
- Kyle Orwig
- University of Pittsburgh
  
- Limited data collection with de-identified tissue

NIH U.S. National Library of Medicine

*ClinicalTrials.gov*

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[Home](#) > [Search Results](#) > Study Record Detail

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**Testicular Tissue Cryopreservation for Fertility Preservation**



# TTC Database

- **PI-** Holly Hoefgen, MD at Washington University St. Louis
  - HollyHoefgen@wustl.edu
- **Population:** all patients who undergo TTC
- **Purpose:** obtain detailed longitudinal data in order to improve care and answer clinical research questions regarding impact of TTC
- **Participation:** all sites with active TTC protocols
- **Need to address:**
  - IRB central or peripheral
  - New data sharing agreements
- **Need to brainstorm:**
  - Data collections sheets- need to be updated to maximize useful information



# New Proposal: National Oncofertility Database Network

**Proposal: Establish a data coordinating center at the University of Colorado as a collaboration with the Oncofertility Consortium**

## Methods:

- Create a steering committee for the database network
- Establish data querying and authorship guidelines
- Establish initial Aims for the database
- Establish a flowsheet to capture EMR data
- Distribute flowsheet to initial participating (pilot) centers
- Export EMR data into REDCap
- Collect data
- Study Aims
- Publish

**Financial support: Internal funding at University of Colorado Denver Anschutz Medical Center**

## UC Denver Personnel:

- Leslie Appiah, MD
- Mary Sammel, PhD
- Angela J. Fought, MS
- Nanette Santoro, MD
- APP nurse navigator
- Research coordinator (1.0 FTE Oncofertility Program)
- Statistician
- Regulatory team



# National Oncofertility Database Network

## Discussion:

- What support is needed at collaborating centers to implement flowsheet and export data?
- Which sites to recruit as a pilot center? How many initial sites are reasonable?
- Will we make the data available only to the participating sites or will we make this freely available data that anyone can request to use?





# Thank You

- Krista Childress, MD-
  - [krista.childress@emory.edu](mailto:krista.childress@emory.edu)
- Maggie Dwiggins, MD-
  - [Maggie.dwiggins@nortonhealthcare.org](mailto:Maggie.dwiggins@nortonhealthcare.org)
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